

ROUTING SLIP FOR RCRA INSPECTION REPORTS

From: CLINT SEITER

Facility Name: WATSON PHARMACEUTICALS

	Initials	Date
1. Lead Inspector (Report Writer):	CTS	10/30/12
- RCRA Info Evaluation & Violation Entry (CEI Date)	CTS	10/30/12
- ICIS Entry (Add Compliance Monitoring)		
- RCRA Info Enforcement Entry (102, 105)		
- EJ Maps		
2. 2nd Inspector (Reviewer):	JAS	10/31/12
3. QA/QC Team Reviewer (Formal Actions Only):		
4. Supervisor:	Jmr	12/26/12
5. Lou Tully:		
6. Lead Inspector (File):		

Notes:



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX**

**75 Hawthorne Street
San Francisco, CA 94105**

<http://www.epa.gov/region9/waste/enforcement/index.html>

Purpose: RCRA Compliance Evaluation Inspection

Facility: Watson Pharmaceuticals

**Location
Address:** 311 Bonnie Circle
Corona, CA 92880

RCRA ID Number: CAD106931488/CAD983665944/CAR000148825/
CAD981631922

**Date of Inspection:
Time In/Time Out** August 29, 2012

EPA Representatives: Clint Seiter
(415) 972-3298
seiter.clint@epa.gov

Jelani Shareem
(415) 972-3095
shareem.jelani@epa.gov

**CUPA and/or State
Representative(s):
Representative(s):** Bernd Schleicher, Haz Materials Management Specialist
Riverside County Dept. of Environmental Health
BSchleic@rivcocha.org
(951) 520-8319

Facility Representative(s): Tony Scrudato, Manager, EH&S
(951) 493-9634
anthony.scrudato@watson.com32

Report Date: October 30, 2012

**Report Prepared
by:** Clint Seiter

A. Introduction

On August 29, 2012 representatives of the U.S. Environmental Protection Agency (EPA) and the Riverside County Department of Environmental Health conducted an unannounced hazardous waste management compliance evaluation inspection (CEI) of the Watson Pharmaceuticals facilities (Watson or the facility) located in Corona, CA. The purpose of the inspection was to determine Watson's compliance with applicable federal environmental statutes and regulations, and in particular, the Resource Conservation and Recovery Act (RCRA), as amended, the regulations provided in the Code of Federal Regulations (CFR), Chapter 40, Parts 261-265, 268, 273, and 279, and the California Code of Regulations (CCR), Title 22, Division 4.5 and the California Health and Safety Code, Division 20.

Facility Background

Company Web Site	www.watson.com
Site History	The Corona Watson Pharmaceutical has been in operation as a manufacturing facility since April, 2011
Number of Employees	Approximately 900 workers are employed in all the combined Watson facilities
Hours of Operation	8 a.m. to 5:00 p.m., Monday through Friday.
Latitude/Longitude	Longitude: 33.883353 Latitude: -117.59853
Facility Operations	<p>Watson Pharmaceuticals, Inc. is a global pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic, brand and biologic pharmaceutical products.</p> <p>Watson Pharmaceuticals in Corona, CA consists of five buildings which, although not "contiguous" are located close to each other. With the exception of Building 3, which is a former warehouse, each building generates hazardous wastes and has its own individual EPA identification number. Building 1 primarily manufactures hydrocodone, a generic pain reliever. Medication for mood disorders and diabetes are also manufactured in this building. Building 2 is used primarily to manufacture oral contraceptives. Building 4 was originally a research and development lab, but now is primarily a warehouse and office space. There is still a small laboratory on the premises which develops quality control methods to be used in other labs. Building 5 is used primarily as a warehouse and packaging operation.</p>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION IX

75 Hawthorne Street
San Francisco, CA 94105-3901
November 26, 2012

In reply, refer to WST-3

Mr. Tony Scrudato
Manager, EH&S
Watson Pharmaceuticals
311 Bonnie Circle
Corona, CA 92880

Re: Warning Letter and Certification of Violation Correction for Watson Pharmaceuticals

Dear Mr. Scrudato:

On August 29, 2012, a hazardous waste investigation was conducted by representatives of the United States Environmental Protection Agency ("EPA"), accompanied by representatives from the Riverside County Department of Environmental Health at Watson Pharmaceuticals, located at 311 Bonnie Circle, Corona, CA. EPA Identification Numbers CAD106931488/CAD983665944/CAR000148825/CAD981631922. During the course of this investigation, information was gathered in accordance with Section 3007 of the Resource Conservation and Recovery Act ("RCRA"), as amended [42 U.S.C. 6927]. A copy of the investigation report is enclosed for your information. The report describes conditions at the facility at the time of the investigation, and identifies areas of noncompliance (corrected during the inspection) with RCRA regulations and a potential violation of the California authorized program under RCRA Subtitle C. Any omissions in the report shall not be construed as a determination of compliance with all applicable regulations.

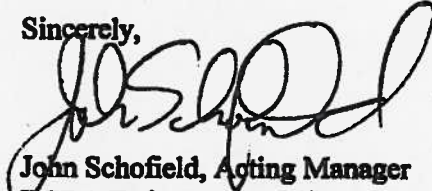
EPA routinely provides copies of investigation reports to state agencies, and upon request, to the public. Such releases are handled according to the Freedom of Information Act regulations (40 CFR Part 2). If you believe this report contains privileged or confidential information, you may make a claim within fourteen (14) calendar days from the date of receipt of this letter. EPA will construe your failure to furnish a timely claim as a waiver of the confidentiality claim.

By copy of this letter, U.S. EPA is providing the State of California with notice of the referenced violations of Subtitle C of RCRA and the California hazardous waste program. U.S. EPA is also providing the State with notice that it intends to take no further enforcement action for the violations noted. The State of California may notify U.S. EPA of its intent to assume or decline responsibility to take further action to address the referenced violations.

Watson Pharmaceuticals should continue to take the necessary steps to maintain and ensure compliance with all applicable Federal, State and local environmental requirements. If

you have questions related to technical aspects of the investigation report or this letter, please contact Clint Seiter at (415) 972-3298 or email him at seiter.clint@epa.gov.

Sincerely,



John Schofield, Acting Manager
RCRA Enforcement Office

Enclosure

cc: K Green, DTSC

Bernd Schleicher, Riverside County Department of Environmental Health



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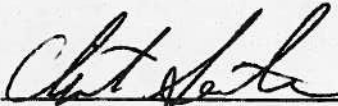
EPA Representatives: Clint Seiter
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Jelani Shareem
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RCRA and Non-RCRA Hazardous Wastes Streams	Per Building 1's 2011 Biennial Report, the CAD106931488 facility generates the following hazardous wastes:	
	Hazardous Waste Name	Hazardous Waste Code
	Cleaning solvent waste	D001/D035/D039/F002/F003/CA343
	High-performance liquid chromatography (HPLC) vials	D001/F003/CA212
	Paper, rags and debris containing flammable liquids	D001/F003/CA214
	Solvent containing wipes	D001/CA212
	<p>Due to the fact that the other three facilities are small quantity generators, these facilities are not required to submit Biennial Reports. Per the California Department of Toxic Substances (DTSC) database, the facilities generate the following hazardous wastes:</p> <ul style="list-style-type: none"> - Building 2: ignitable solvents (D001)/non-halogenated solvents (F003); organic liquid mixture (CA343); pharmaceutical waste (CA311)/oxygenated solvents (CA212); - Building 4: ignitable solvents (D001)/pharmaceutical wastes (CA311)/off-spec, aged or surplus inorganics (CA141); - Building 5: non-halogenated solvents (F003)/ignitable solvents (D001)/oxygenated solvents (CA212)/pharmaceutical waste (CA311). 	
Generator Status	Building 1 (CAD106931488) is a large quantity generator, and the other three buildings that generate hazardous wastes (CAD983665944, CAR000148825, CAD981631922) are small quantity generators.	
Compliance History	Per EPA's inspection/enforcement database, Building 1 (CAD106931488) was last inspected by DTSC on February 28, 1993. No violations were noted. The database shows no record of the other three buildings being previously inspected.	
SIC/NAICS Codes	SIC: 2834 NAIC:325412	

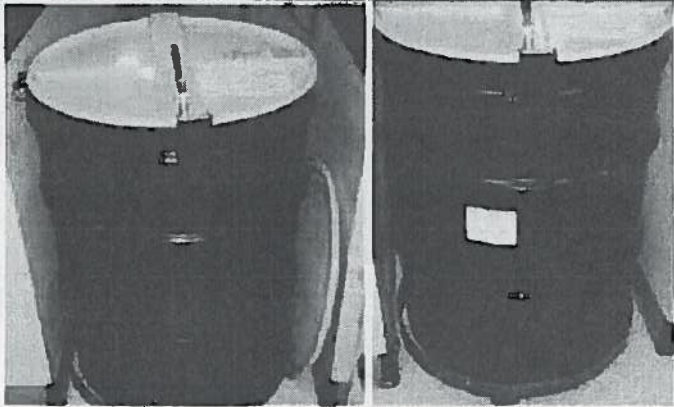
B. On-Site Inspection


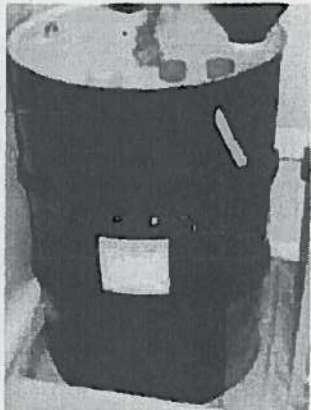
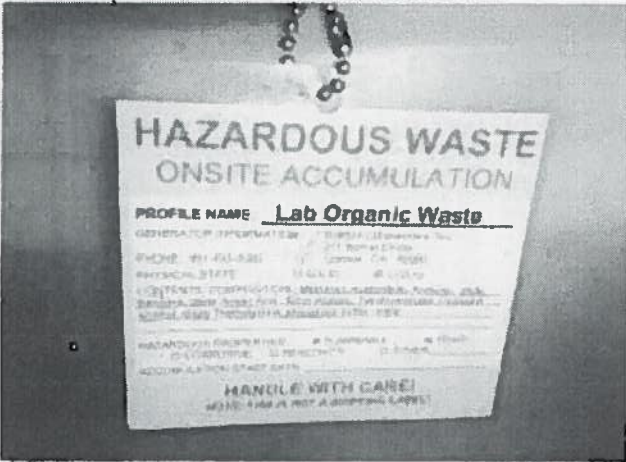
The following areas were inspected: the Building 1 R&D Lab, with its satellite accumulation area; the Hydro Testing Lab, with its: high performance liquid chromatography (HPLC) and accompanying satellite accumulation areas; and the Universal Waste Storage Area. In all these areas, all hazardous waste containers were correctly labeled, closed and in good condition.

1. Building 1 (CAD106931488): Waste Accumulation Area (less than 90 day hazardous waste accumulation area)

This area consists of two lockers. All employees with access to the locker interiors are required to carry cell phones. An Ansul system protects the area against fire. There was a total of four 55-gallon containers and a shelf of lab packs. All containers were closed, labeled properly and in good condition.

2. Building 4 (CAD983665944)

Observation	Photograph
Technical Services Lab: one 55-gallon satellite accumulation drum containing discarded lab vials was unlabeled (corrected)	 Unlabeled 55-gallon drum/ same drum now labeled

Observation	Photograph
<p>Technical Services Lab: second unlabeled 55-gallon satellite container (corrected)</p>	<div data-bbox="743 428 1094 863">  </div> <div data-bbox="1101 457 1409 863">  </div> <p>Unlabeled 55-gallon drum/ same drum now labeled</p>
<p>Research and Development Lab: the label of one 1-gallon satellite accumulation container lacked an accumulation start date (corrected).</p>	<div data-bbox="743 940 1365 1398">  </div> <p>Satellite accumulation container w/o accumulation start date</p>

C. Record Review

Record	Year(s)	Observation(s)
Manifests	2010-2012	Reviewed
Land Disposal Restriction ("LDR") Notifications	2010-2012	Reviewed
Biennial Report (for CAD106931488, the only LQG)	2011	Reviewed
Contingency Plan (Business Plan)	Current	Reviewed
Inspection checklists	Current	Reviewed
Training Records and Documentation	Current	Reviewed

Watson Pharmaceuticals
CAR000148825/CAD981631922/
CAD106931488/CAD983665944

POTENTIAL VIOLATIONS
CCR Title 22 and RCRA 40 CFR (Hazardous Waste Management Regulations)

NO.	STATUTE OR REGULATION	REGULATION SUMMARY	FINDING(s)	FACILITY RESPONSE
	<p>Title 22 §66262.34(e)(1)(C);</p> <p>Title 22 §66262.34(e)(1)(E), (f)(3)</p> <p>(40 CFR §262.34(c)(1)(ii))</p>	<p>Generators who accumulate hazardous waste on site without a permit or grant of interim status shall comply with the following requirements:</p> <p>(1) the date upon which each period of accumulation begins shall be clearly marked and visible for inspection on each container;</p> <p>(2) the date the applicable accumulation period begins, and</p> <p>(3) each container and tank used for onsite accumulation of hazardous waste shall be labeled or marked clearly with the words, "Hazardous Waste." Additionally, all containers shall be labeled with the following information:</p> <p>(A) composition and physical state of the wastes;</p> <p>(B) statement or statements which call attention to the particular hazardous properties of the waste (e.g., flammable, reactive, etc.);</p> <p>(C) name and address of the person producing the waste.</p>	<p>- Two 55-gallon satellite accumulation containers in the Technical Services Lab in Building 4 (CAD983665944) were unlabeled (corrected);</p> <p>- One 1-gallon satellite accumulation container in the R&D lab lacked an accumulation start date (corrected).</p>	<p>Corrected during the inspection</p>

Watson Pharmaceuticals
CAR000148825/CAD981631922/
CAD106931488/CAD983665944

List of Attachments

1. Photograph Log

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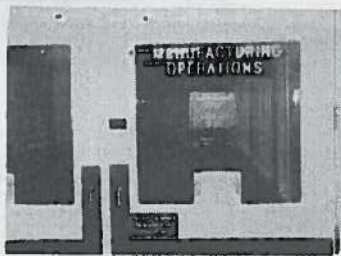
Photograph Log for EPA's August 29, 2012 Watson Pharmaceuticals RCRA Inspection

All photographs on this log were taken with a digital camera by Jelani Shareem, RCRA Enforcement Office, EPA Region IX. Please note that each photograph number begins with "P8290" and that the photograph log starts with photograph number 384.

- 384. Door to manufacturing area
- 385. R&D lab: hazardous waste locker in SAA-1-005
- 386. SAA-1-005 sign
- 387. SAA-1-005 locker interior
- 388. SAA-1-005 locker interior, top shelf
- 389. SAA-1-005 drum label close-up
- 390. SAA-1-005 drum label close-up
- 391. SAA-1-005 weekly inspection log
- 392. Hydro testing lab, "HPLC WASTE" label
- 393. High-performance liquid chromatography (HPLC) waste container
- 394. HPLC label
- 395. SSA-1-001 satellite accumulation area sign
- 396. SSA-1-001 satellite accumulation container
- 397. SSA-1-001 satellite accumulation container, label close-up
- 398. Satellite accumulation area list of procedures
- 399. SSA-1-002 satellite accumulation area sign
- 400. SSA-1-002 satellite accumulation container
- 401. SSA-1-002 satellite accumulation container, label close-up
- 402. Cart with hazardous waste containers from labs

- 403. Hazardous waste storage area (HWSA) locker
- 404. HWSA locker
- 405. Four hazardous waste containers in locker
- 406. Label close-up
- 407. Label close-up
- 408. Label close-up
- 409. Label close-up
- 410. Shelves of hazardous waste containers pulled from labs
- 411. Label close-up
- 412. Label close-up
- 413. Label close-up
- 414. Label close-up
- 415. Label close-up
- 416. Label close-up
- 417. Universal waste storage area label
- 418. Universal waste storage area
- 419. Universal wastes
- 420. Alarm system
- 421. HWSA waste locker #2
- 422. One 55-gallon drum of hazardous waste in locker
- 423. Label close-up
- 424. HWSA #2 weekly inspection log
- 425. Building 2 warehouse satellite accumulation area locker (SAA-2-003)

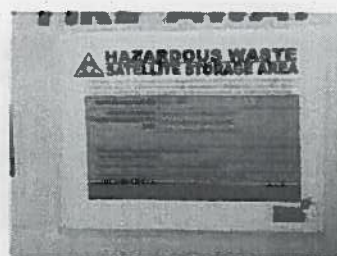
- 426. SAA-2-003 label close-up
- 427. 55-gallon satellite accumulation container in locker
- 428. Drum label close-up
- 429. Building 4 HWSA locker (no containers inside)
- 430. Photo error
- 431. Unlabeled satellite accumulation container in technical services lab
- 432. Container with new label
- 433. Label close-up
- 434. Label for SAA-4-002 satellite accumulation area
- 435. Unlabeled satellite accumulation container in technical services lab
- 436. Cabinet interior
- 437. Container with new label
- 438. Label for SAA-4-001 satellite accumulation area
- 439. Lab satellite accumulation container labeled, but without accumulation start date
- 440. Label close-up
- 441. Cart of inventoried chemicals awaiting a waste determination
- 442. Building 5 hazardous waste storage locker
- 443. Hazardous waste container in storage locker
- 444. Label close-up



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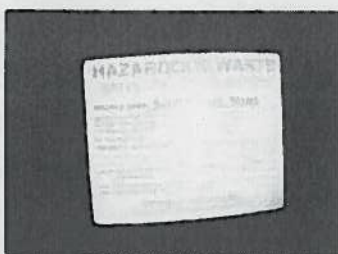
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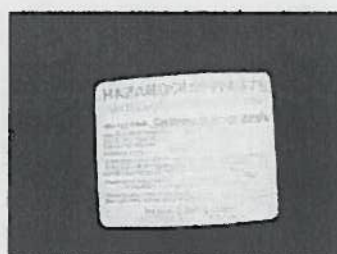
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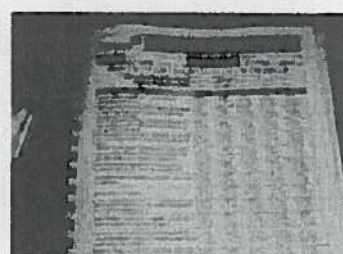
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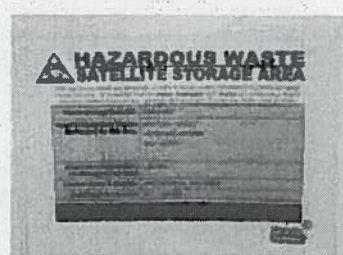
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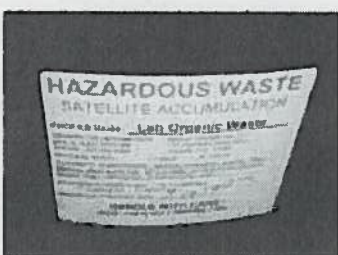
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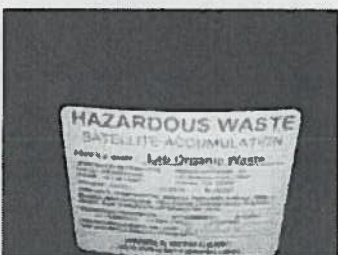
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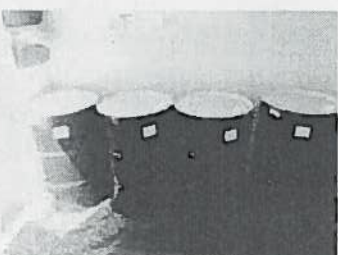
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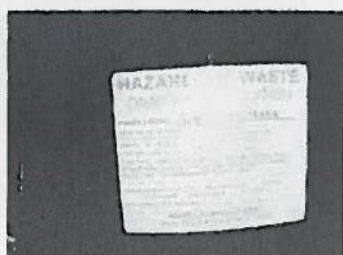
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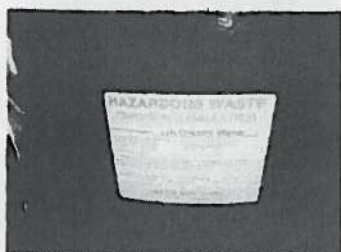
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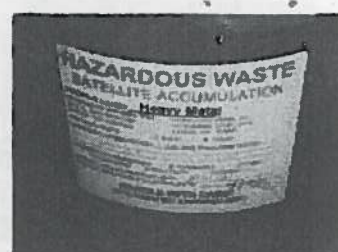
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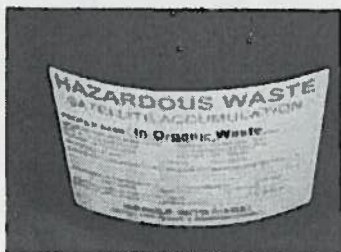
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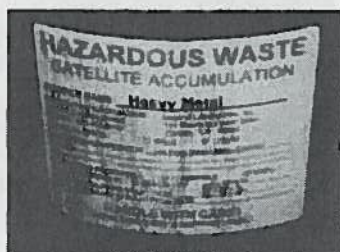
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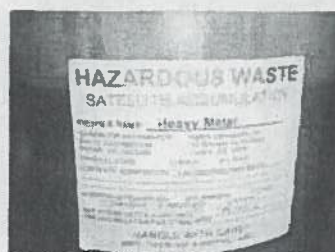
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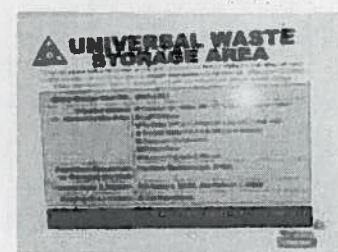
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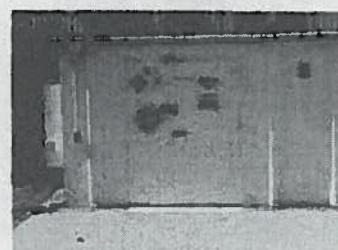
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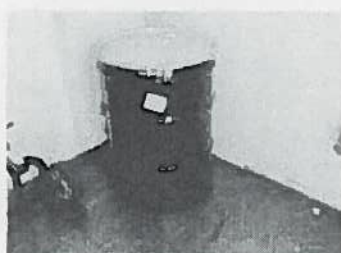
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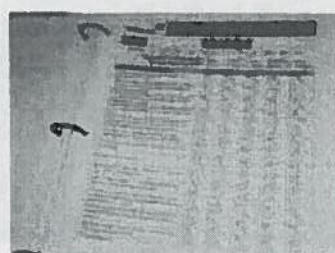
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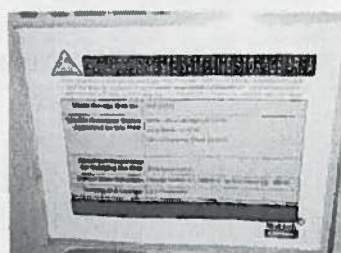
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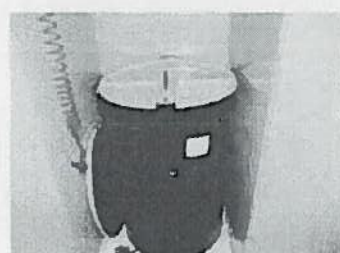
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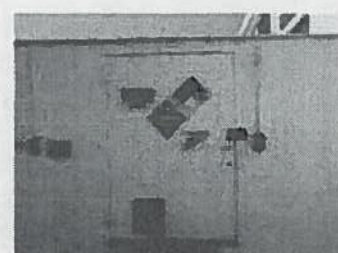
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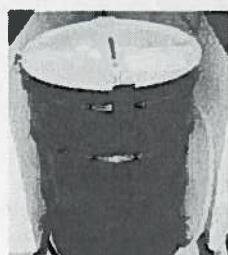
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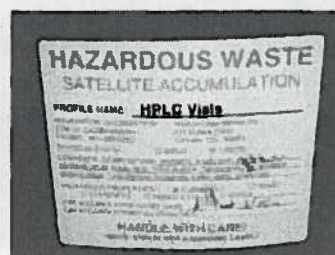
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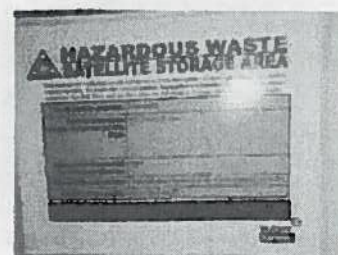
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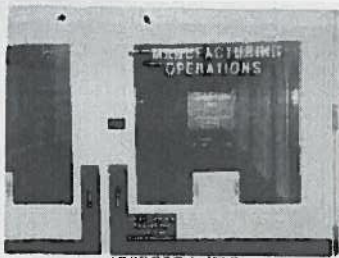
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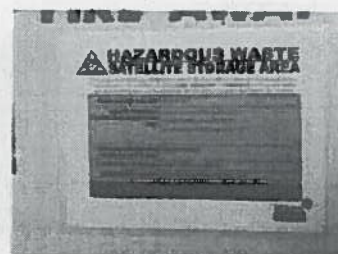
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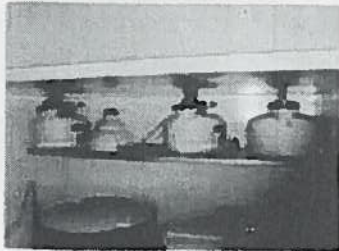
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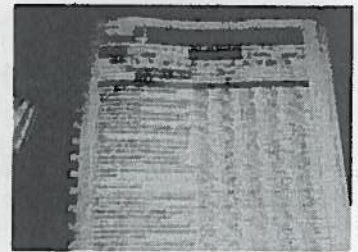
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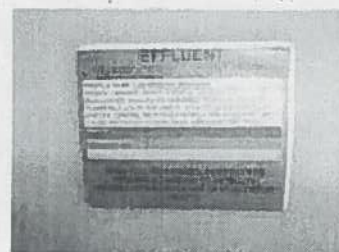
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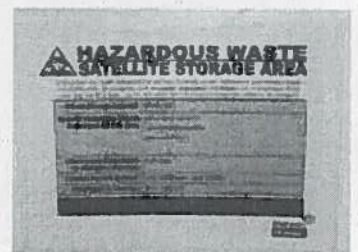
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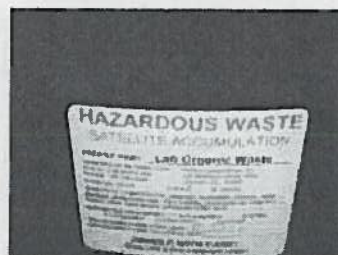
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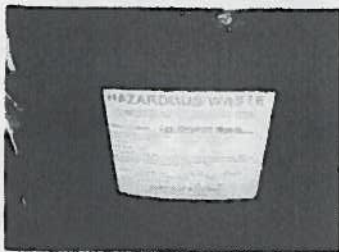
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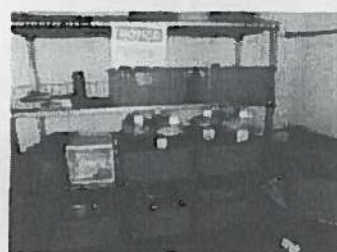
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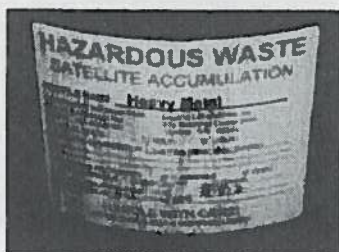
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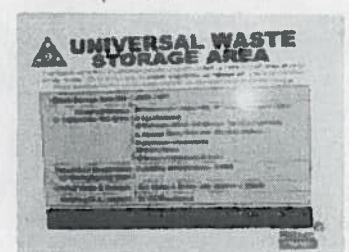
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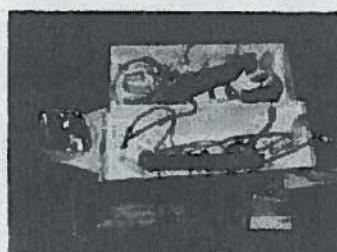
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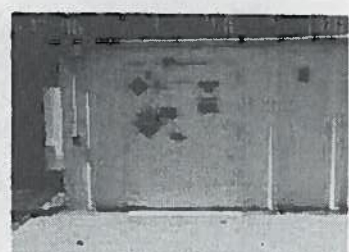
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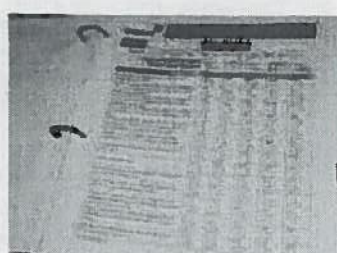
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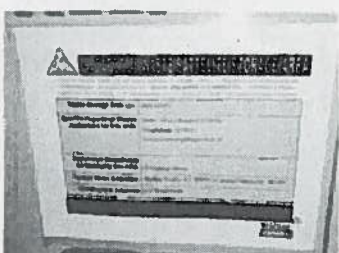
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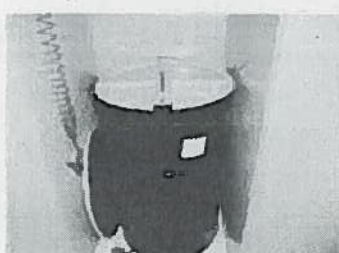
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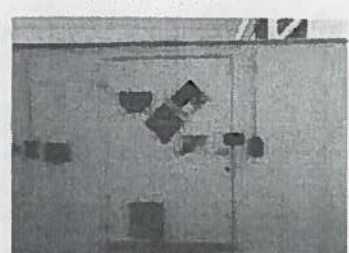
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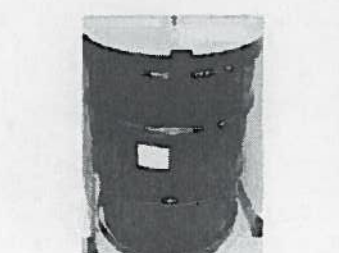
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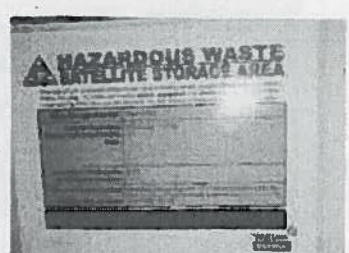
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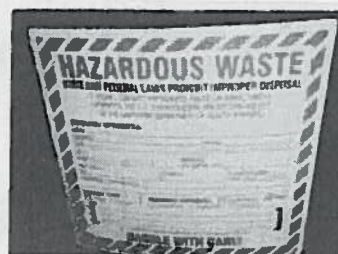
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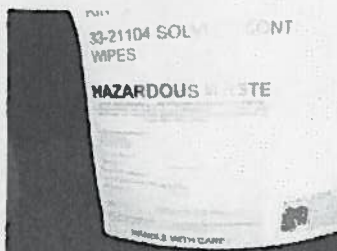
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COPY

OMB# 2050-0024; Expires 12/31/2014

<p>SEND COMPLETED FORM TO: The Appropriate State or Regional Office.</p>	<p>United States Environmental Protection Agency RCRA SUBTITLE C SITE IDENTIFICATION FORM</p>	
<p>1. Reason for Submittal</p> <p>MARK ALL BOX(ES) THAT APPLY</p>	<p>Reason for Submittal:</p> <p><input type="checkbox"/> To provide an Initial Notification (first time submitting site identification information / to obtain an EPA ID number for this location)</p> <p><input type="checkbox"/> To provide a Subsequent Notification (to update site identification information for this location)</p> <p><input type="checkbox"/> As a component of a First RCRA Hazardous Waste Part A Permit Application</p> <p><input type="checkbox"/> As a component of a Revised RCRA Hazardous Waste Part A Permit Application (Amendment # _____)</p> <p><input checked="" type="checkbox"/> As a component of the Hazardous Waste Report (If marked, see sub-bullet below)</p> <p><input checked="" type="checkbox"/> Site was a TSD facility and/or generator of $\geq 1,000$ kg of hazardous waste, >1 kg of acute hazardous waste, or >100 kg of acute hazardous waste spill cleanup in one or more months of the report year (or State equivalent LQG regulations)</p>	
<p>2. Site EPA ID Number</p>	<p>EPA ID Number <u>C A 1 0 1 9 2 3 6 6 5 9 4 4</u></p>	
<p>3. Site Name</p>	<p>Name: <u>WATSON LABORATORIES</u></p>	
<p>4. Site Location Information</p>	<p>Street Address: <u>311 BONNIE CIRCLE</u></p> <p>City, Town, or Village: <u>CORONA</u> County: <u>RIVERSIDE</u></p> <p>State: <u>CALIFORNIA</u> Country: <u>USA</u> Zip Code: <u>92880</u></p>	
<p>5. Site Land Type</p>	<p><input checked="" type="checkbox"/> Private <input type="checkbox"/> County <input type="checkbox"/> District <input type="checkbox"/> Federal <input type="checkbox"/> Tribal <input type="checkbox"/> Municipal <input type="checkbox"/> State <input type="checkbox"/> Other</p>	
<p>6. NAICS Code(s) for the Site (at least 5-digit codes)</p>	<p>A. <u>541710</u> C. <u> </u></p> <p>B. <u> </u> D. <u> </u></p>	
<p>7. Site Mailing Address</p>	<p>Street or P.O. Box: <u>311 BONNIE CIRCLE</u></p> <p>City, Town, or Village: <u>CORONA</u></p> <p>State: <u>CALIFORNIA</u> Country: <u>USA</u> Zip Code: <u>92880</u></p>	
<p>8. Site Contact Person</p>	<p>First Name: <u>TONY</u> MI: <u> </u> Last: <u>SCRIVATO</u></p> <p>Title: <u>MANAGER, EHS</u></p> <p>Street or P.O. Box: <u>311 BONNIE CIRCLE</u></p> <p>City, Town or Village: <u>CORONA</u></p> <p>State: <u>CALIFORNIA</u> Country: <u>USA</u> Zip Code: <u>92880</u></p> <p>Email: <u>ANTHONY.SCRIVATO@WATSON.COM</u></p> <p>Phone: <u>951-493-5300</u> Ext.: <u> </u> Fax: <u> </u></p>	
<p>9. Legal Owner and Operator of the Site</p>	<p>A. Name of Site's Legal Owner: <u>WATSON PHARMACEUTICALS INC</u></p> <p>Owner Type: <input checked="" type="checkbox"/> Private <input type="checkbox"/> County <input type="checkbox"/> District <input type="checkbox"/> Federal <input type="checkbox"/> Tribal <input type="checkbox"/> Municipal <input type="checkbox"/> State <input type="checkbox"/> Other</p> <p>Street or P.O. Box: <u>311 BONNIE CIRCLE</u></p> <p>City, Town, or Village: <u>CORONA</u> Phone: <u>951-493-5300</u></p> <p>State: <u>CALIFORNIA</u> Country: <u>USA</u> Zip Code: <u>92880</u></p> <p>B. Name of Site's Operator: <u>WATSON PHARMACEUTICALS INC</u></p> <p>Operator Type: <input checked="" type="checkbox"/> Private <input type="checkbox"/> County <input type="checkbox"/> District <input type="checkbox"/> Federal <input type="checkbox"/> Tribal <input type="checkbox"/> Municipal <input type="checkbox"/> State <input type="checkbox"/> Other</p> <p>Date Became Owner: <u>10-1-84</u></p> <p>Date Became Operator: <u>10-1-84</u></p>	